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In re Application of :
WALLACH et al :
Serial No. : 09/445,223 :
Filed : 22 February, 2000 :
Attorney Docket No. : WALLACH=24 :

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.144, filed on 26 March 2004. The delay in acting upon this petition is regretted.

BACKGROUND

This application is filed as 35 USC 371 of the National Stage filing of PCT/IL98/00255, filed 01 June 1998.

A review of the file history shows that the Office made a restriction requirement under PCT Rule 13.1 of claims 1-39 into twenty groups and subsequently made final. In particular, the following lack of unity between groups I and II is at issue:

Group I, original claims 1-8, 11, 23, 24-26, drawn to DNA sequence encoding B1 protein.

Group II, original claims 9-10, 22, 24-26 and 38, drawn to B1 protein, isoforms, fragments or analogs thereof.

Applicants elected group I, claims 1-8, 11, 23-26 with traverse, and canceled/deleted claims 1-4, 9, 10, 13, 18, 20-21, 25-28, 38-39, and added new claims 40-50, in the response filed on 29 May 2001.

Examiner addressed applicants traversal regarding the restriction between groups I, and II and rest of all the groups. Examiner has examined claims 5-8, 11,23-24, 44-48, drawn to DNA sequences encoding B1 protein, fragments, analogs and derivatives thereof, and withdrew claims 12, 14-17, 19, 22, 29-37, 40-43, 49-50 as drawn to non-elected invention. The restriction requirement was made final in the office action mailed on 15 January 2004.

The petition to review the unity of invention requirement set forth by the examiner, was filed on 26 March 2004.

Subsequent to the filing of the petition, an after final amendment was filed by applicants on 11 May 2004.

RELEVANT AUTHORITY

An international or a national stage application are considered to have unity of invention where there exists a "special technical feature" that defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See PCT Rule 13.2; 37 CFR 1.475(a), (b)(1) and (2).

In addition to the categories provided for in 37 CF 1.475(b) (1-5), unity of invention is explicitly provided for in the following context:

Claim 1: Protein X
Claim 2: DNA sequence encoding protein X.

wherein, expression of the DNA sequence in a host results in the production of a protein, which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity of invention between claims 1 and 2 is accepted.

See MPEP 1893.03(d) and Annex B, Part 2 of the PCT Administration Instructions, Example 17.

Unity of invention has to be considered in the first place only in relation to the independent claims in an international and not the dependent claims and
(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims;
(ii) If however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on the claim need to be carefully considered. If there is no link remaining an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised. See ANNEX B: Unity of Invention Part 1 "Instructions Concerning Unity of Invention" MPEP AI-6 (Rev. 1. Feb. 2003).

DISCUSSION

The above-identified application is a national stage application submitted under 35 U.S.C. 371 to which "unity of invention", and not U.S. restriction practice is applicable. MPEP section 189.03(d). The lack of unity between the group I and group II, especially between nucleic acid encoding the peptide of SEQ ID NO: 1 and the peptide of SEQ ID NO: 1 are at issue.

Representative claims of group I:

Amended Claim 44: An isolated DNA sequence encoding a polypeptide which potentiates cell death, said polypeptide consisting of: a) a sequence comprising SEQ ID NO: 1; b) a sequence comprising an analog of a) having no more than ten changes in the amino acid sequence of a), each said change being substitution, deletion or insertion of a single amino acid, which analog potentiates cell death; c) a fragment of sequence of SEQ ID NO: 1, which fragment potentiates cell death.

Claim 51: An oligonucleotide molecule consisting of an antisense sequence of at least a part of an mRNA sequence corresponding to a DNA sequence according to claim 44.

Representative claims of group II:

Amended Claim 40: An isolated polypeptide which potentiates cell death, said polypeptide consisting of a) a sequence comprising SEQ ID NO: 1; b) a sequence comprising an analog of a) having no more than ten changes in the amino acid sequence of a), each said change being substitution, deletion or insertion of a single amino acid, which analog potentiates cell death; c) a fragment of sequence of SEQ ID O: 1, which fragment potentiates cell death.

Applicant argues that in accordance with PCT Administration Instructions, Example 17, the claims of group I and group II possess unity of invention.

It is noted that the independent claims 40 and 44 above, are drawn to a genus of nucleotides encoding a genus of polypeptides whereas the example 17 represents a single species of a protein and a genus of nucleic acids, which encode the protein.

Example 17 specifically indicates that unity of invention between the protein and its corresponding encoding DNA sequence requires that protein and the DNA sequence exhibit corresponding special technical features.

The polynucleotide of group I does not share a common structure or function or property with the polypeptide of group II. Further neither the nucleotide sequence encoding the fragments of sequence of SEQ ID NO: 1, nor the oligonucleotide molecule consisting of antisense sequence of a part of mRNA encode the protein of SEQ ID NO: 1 do not exhibit corresponding special technical feature as required by the PCT Administration Instructions, Example 17.

Further according to the PCT Rule 13.2, the special technical feature shall mean those technical features that define contribution which each of the claimed inventions, considered as whole makes over the prior art.

The technical feature of group I is considered as polynucleotide.
The technical feature of group II is considered as polypeptide.
The polynucleotide is made of nucleic acids, and the polypeptide is made of amino acids.
Thus, the polynucleotides of group I, and the polypeptides of group II are not linked by the same technical feature as defined by PCT Rule 13.2.

In the present instance neither the polynucleotides of group I and nor the polypeptides of group II exhibit a corresponding special technical feature since Pickup et al (US Patent 5,578,468) teaches a sequence consisting of 37 nucleotides SEQ ID NO: 44 (which is 100 % similar to the SEQ ID NO: 2 of the instant claims which encodes the amino acid sequence of SEQ IDNO: 1, from nucleotides 2067 to nucleotides 2098) which is within the scope of the presently claimed application. It is noted that since the claim 51 recites 'oligonucleotide sequence consisting of antisense sequence of at least part of an mRNA sequence to a DNA sequence of claim 44' and the specification disclosure does not define the antisense sequence length or mRNA sequence that corresponds to sequence of claim 44, the reference sequence would anticipate the claim 51 onligonucleotiode sequence. See the attached sequence alignment.
Thus, polynucleotides of group I do not share a special technical feature with the polypeptides of group II.

Upon reconsideration, the Finality of the office action has been withdrawn as being premature. The application will be forwarded to the examiner for preparation of an action consistent to this petition decision.

DECISION

Applicant's petition for reconsideration of Lack of Unity requirement between groups I-II under 37 CFR 1.144 is **DENIED** for the reasons set forth above.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.

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